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No. .....

Supreme Court, U. S.
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In the
Supreme Court of the United States

OCTOBER TERM, 1972

72-113

STERLING DRUG, INC., *Petitioner,*

vs.

ANNA T. SINGER and LESLIE SINGER, *Respondents.*

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

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vs.

ANNA T. SINGER and LESLIE SINGER, *Respondents.*

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

Petitioner STERLING DRUG, INC., defendant below, respectfully prays that a writ of certiorari issue to review the judgment and opinion of the United States Court of Appeals for the Seventh Circuit entered in this case on April 21, 1972.

OPINION BELOW

The opinion of the Court of Appeals has not yet been reported and appears in Appendix I hereto.

JURISDICTION

The judgment of the Court of Appeals for the Seventh Circuit was entered on April 21, 1972. A timely petition for rehearing was denied on June 5, 1972. See Appendix II. The

jurisdiction of this Court is invoked under 28 U.S.C. § 1254 (1).

QUESTIONS PRESENTED

1. Whether the Court of Appeals applied the proper standards in reversing the judgment of the trial court entered on a jury verdict in favor of this petitioner and remanding the case for a trial on damages only.

2. Whether the Court of Appeals has denied petitioner due process by depriving it of its right to a jury trial on the question of liability.

STATEMENT OF THE CASE

Jurisdiction of this common law action in the district court was invoked because of diversity of citizenship, plaintiffs being citizens of Indiana and the defendant being incorporated in Delaware. The action arose as a result of plaintiff's ingestion of a certain prescription drug manufactured by the defendant under the trade name Aralen. The plaintiff claimed that the defendant marketed the drug Aralen in an unreasonably dangerous and unsafe condition for its intended use and that as a result plaintiff, Anna Singer, lost practically all of her vision in both eyes.

The crux of the dispute at the jury trial was whether plaintiff, Anna Singer, had improperly obtained refills of an original prescription from a local druggist and had continued to take the prescription drug for a period of approximately seven years without being under the care and supervision of a physician. It was undisputed that plaintiff was suffering from a chronic incurable disease known as lupus erythematosus which can cause blindness and that her physician had originally prescribed Aralen in an attempt to control the disease. Also strongly in contention was the sufficiency and timeliness of defendant's warnings of side effects in the form of visual disturbances.

After a lengthy jury trial the jury returned a verdict finding for the defendant and the trial court entered judgment thereon. Plaintiffs' motion for a new trial was denied.

REASONS FOR GRANTING THE WRIT

While Petitioner feels, and strongly urged in the Court of Appeals, that the verdict of the jury and the judgment entered thereon was and is merited by the record, the principal thrust of this Petition is the impropriety and injustice of that part of the Court of Appeals order reversing the case for a new trial on damages only, which deprives the defendant of a jury trial on liability and constitutes a judicial determination that an admittedly valuable prescription drug, Aralen, is *per se* a drug which should not be on the market.

I.

THE RECORD IS REPLETE WITH DISPUTED QUESTIONS OF FACT WHICH DEFENDANT HAS A CONSTITUTIONAL RIGHT TO HAVE PASSED UPON BY A JURY.

The holding by the appeals court that Sterling Drug, as a matter of law did not give adequate warning to users of its prescription drug, Aralen, regardless of time or times of ingestion, and the holding, as a matter of law, that there was no triable issue of fact concerning the plaintiff's use or misuse thereof is without precedent, not only as to decisions in Aralen cases in other circuits and other jurisdictions but also as to prescription drug litigation generally where no impure drug is involved. Such a holding is particularly inappropriate in the case at bar where there are multiple, serious, material factual disputes as to whether plaintiff was taking the prescription drug in accordance with the directions and under the supervision and care of a physician.

We respectfully submit that the court of appeals has overlooked, or misapprehended the following points which vitally affect the underpinning of the Court's rationale for the remandment of this case for a trial on damages only:

Misuse of Aralen by Plaintiff

1. In its opinion, the Court of Appeals, in considering the question of the misuse by plaintiff Anna Singer of the prescription drug Aralen, says:

> "We have read the testimony relied on by Sterling and find no substantial evidence of Anna Singer's misuse of Aralen through excessive dosage or through 'exposure to hot sun' during her European trip."

This sentence neither correctly, nor at all adequately, represents the evidence or Sterling's contention with reference to this point. First of all, the evidence and arguments relating to Anna Singer's "exposure to hot sun" by taking a trip through Southern Europe and North Africa during the summer months was not only concerned with plaintiff's use of Aralen but with her conduct generally, and the question of whether there was an aggravation of her lupus disease, an incurable condition characterized by exacerbation and remissions. A substantial issue raised by the trip in question was whether plaintiff's undisputed photo-sensitivity, which she admitted caused her physician to advise her to avoid the summer sun (even in Indiana), exacerbated or "lighted up" her lupus disease so that it affected her eyes and vision.

Dr. Tuffanelli, an undisputed authority on the disease, clearly stated that lupus could cause retinopathy and that people with this disease, should definitely avoid over-exposure to hot sun. The defendant has the right to have a jury decide whether plaintiff herself had caused her loss of vision and damages by voluntarily exposing herself to such hot sun conditions.

2. The "excessive dosage" question is also a very real triable issue, not only as to the number of tablets plaintiff was taking per day, but also as to whether or not even the recommended dosage should have been reduced, or eliminated altogether, if plaintiff, Anna Singer, had really been taking the drug "under the supervision and care of a physician" as she contended. Defendant Sterling, as far back as 1960, had advised physicians in its "product information card" that "macular lesions and narrowed retinal vessels, and the scotomatous vision and field defects to which they gave rise, although evidently irreversible, ceased to progress on discontinuation of therapy."

In 1961 and 1962 the "product information card" was further amended and physicians prescribing Aralen were further advised that "Periodic ophthalmologic examinations (including slit lamp, finders and visual field examinations) are advisable . . ." These warnings were in 1960, 1961, and 1962 considerably before Sterling's February, 1963, across-the-board mailing of its "Important Drug Precautions" letter to all physicians in the United States concerning possible visual damage from the use of Aralen and advising close supervision of all patients for whom Aralen had been prescribed.

The Record discloses no evidence that plaintiff saw any physician in 1963 before taking her trip, or had any eye examinations, or took any other precautions about her lupus disease except to somehow get a supply of about 100 Aralen tablets from the family druggist-friend without any written prescription—except insofar as she vaguely claimed that Dr. Hoit "arranged for that", a claim completely at variance with Dr. Hoit's testimony and his records. The foregoing presents a clear triable issue of fact as to plaintiff's use of Aralen and whether she did (as she alleges and on which she has the clear burden of proof) use the

product properly under the care and supervision of a physician.

II.

THE RECORD CLEARLY PRESENTS A TRIABLE ISSUE OF FACT AS TO WHETHER STERLING DRUG GAVE ADEQUATE WARNING OF THE SIDE EFFECTS OF ARALEN TO PLAINTIFF'S PHYSICIAN, DR. HOIT AND WHETHER ANY SUCH ALLEGED FAILURE OF WARNING WAS THE PROXIMATE CAUSE OF THE INJURIES COMPLAINED OF. NO COURT, ANYWHERE, IN ANY OTHER ARALEN CASE, HAS DIRECTED A VERDICT AGAINST STERLING.

We are not now considering whether there is any credible evidence in the record to support a jury verdict in favor of the plaintiffs—what is to be considered at this juncture is whether, as a matter of law, the jury's verdict in favor of the defendant Sterling is totally without foundation.

The Court of Appeals overlooked very clear testimony by Dr. Hoit, a witness called by plaintiffs. Standing alone, that testimony is to the effect that the doctor gave plaintiff Anna Singer one non-refillable written Aralen prescription for 21 tablets, on 3-2-57, and that his custom when prescribing medication that requires a written prescription, is to prescribe just enough to last the patient until the next visit so that he can check on the effectiveness of the medication and to determine if the medication shows some side effect. Dr. Hoit stated that he did not recall seeing or hearing from plaintiff again until she came to his office some 7 years later on 4-2-64, and he did not then recognize her as a former patient. Also, he had no recollection of ever having given plaintiff, or any druggist on her behalf, any further prescription, written or oral, during the period 1957 to 1964. With reference to any literature from Sterling relative to Aralen or visits of Sterling "detail men" he

said that in the late '50s or early '60s he recalled several letters from Sterling and he thought he did see somebody but he was not sure since "Winthrop (Sterling) does not detail us routinely".

If this testimony of Dr. Hoit's is given full credence, and the jury was certainly entitled so to do (and apparently did), then the jury would have to conclude that plaintiff's testimony and that of her family druggist was not credible and that plaintiff had therefore taken the prescription drug Aralen for 7 years, without prescription and without the care and supervision of a doctor.

Admittedly, plaintiff's testimony and that of her druggist contradict in some respects plaintiff's witness, Dr. Hoit, but it is up to the jury to weigh the credibility of the evidence and to decide who or what they believe most credible. A clear triable issue of fact is thus presented as to plaintiff's contributory negligence and/or misuse of the product. Also a triable issue of fact is presented as to whether or not Dr. Hoit received, read, or considered the warning literature and other communications from Sterling concerning side effects of Aralen. Plaintiff's counsel in his brief, argued that Dr. Hoit could have been sued for his negligence in the treatment of Mrs. Singer. This could only reasonably mean that Dr. Hoit medicated plaintiff without supervising her treatment, giving her periodic examinations, and not otherwise heeding Sterling's warnings in the Aralen literature about possible visual side effects. If this is the inference to be drawn from the evidence is it consonant with a directed verdict against Sterling on liability?

2. The Court of Appeals states in its opinion "The Singers proved a stronger case than required since the doctrine of strict liability would hold Sterling liable for manufacturing and marketing, without adequate warning, a dangerously defective product like Aralen. Aralen is not,

and has never been held to be by the F.D.A. or by any Court, a "dangerously defective product." To be dangerously defective there would have to exist in the drug some impurity or similar defect, occurring during formulation or manufacture, which would not be in accord with the manufacturer's specification. In this case there is not only no proof of this, there is not even any such contention by the plaintiff. Aralen is a drug which falls in the category of Comment K of Section 402 A of the Restatement of Torts 2d, sometimes called the prescription drug exception to the doctrine of strict liability. Such products are there described as "unavoidably unsafe products" which is not at all the same as a "dangerously defective product," as this Court describes Aralen.

Following is a list of all Aralen decisions, and in not one of these cases was there a directed verdict against Sterling, or a decision holding Sterling liable as a matter of law. In the one case where there was a directed verdict, *Oppenheimer,* it was in favor of Sterling. The evidence on behalf of Sterling in all of these cases was essentially the same since it is preponderantly documentary; the variations in the cases basically revolved around the usage of the drug by the plaintiff, the time, the amount ingested, etc., plus the role played by the various prescribing physicians.

Oppenheimer v. *Sterling Drug, Inc.,* 7 Ohio App. 2d 103. (1964) Directed verdict for defendant upheld on appeal. Said the Court at page 106; "Three other factors enter the treatment picture of the plaintiff, her doctor, the plaintiff herself, and the druggist. In the record before us, there is nothing to indicate that the doctor relied upon any information furnished by the defendant in prescribing Aralen for his patient, the plaintiff herein . . ."

Cochran v. *Brooke,* 243 Ore. 89, 409 Pac. 2d 904. (1966)

The Court there refers to Comment K under Sec. 802A of the Restatement of Torts and says, inter alia,

". . . the liability is still limited to a defective product . . ." "the liability is not absolute." "Whether or not the warning given by Sterling was adequate and timely was a question for the trier of the facts . . ."

Sterling Drug, Inc. v. *Cornish,* 370 F.2d, 82, 84 (1966): "The whole question of the timeliness of appellant's warning was, in our opinion, one upon which reasonable men could differ. The question was therefore properly left to the jury. . . ."

Krug v. *Sterling Drug, Inc.,* 416 S.W. 2d 143 (1967). At page 151: "The issue (reasonableness of Sterling's efforts to warn) was to be resolved by the jury . . ."

Sterling Drug Inc. v. *Yarrow,* 408 F.2d 978 (1969) (Tried by Court without jury) Pg. 990: "These findings of fact were not clearly erroneous." Pg. 994: "Further the expert testimony of Dr. Hazel, to say the least, was subject to evaluation by the trier of the facts. It might be given credit in part or given no credit."

Kershaw v. *Sterling Drug, Inc.,* 415 F.2d 1009 (1969) At page 1012: ". . . questions of fact in this case included the causation of chloroquine retinopathy, Sterling's knowledge of the disease, and the nature of its warnings."

Basko v. *Sterling,* 416 F.2d 417, 427 (1969): ". . . we reject plaintiff's contention that she was entitled to a directed verdict as a matter of law. Since defendant did make various efforts to warn, including the mailing of the 'Dear Doctor' letters, our case is unlike Davis v. Wyeth Laboratories, Inc., supra, where the evidence was overwhelming that the manufacturer not only knew the vaccine was being dispensed at mass clinics without any warning but also attempted to assure all members of the community that they should take the vaccine."

Schenebeck v. *Sterling Drug, Inc.,* 281 F.2d 919, 923 (1970): "Whether or not Sterling's failure to warn proximately caused or contributed to cause Mrs. Schen-

ebeck's blindness was an issue properly submitted to the jury."

Christofferson v. *Kaiser & Winthrop Laboratories Division of Sterling Drug, Inc.*, 92 Cal. Rptr. 825, 827, 828 (1971). "Here there was evidence, both pro and con, as to possible indications of danger discoverable in time to permit effective warning. This fact question was submitted to the jury on instructions which properly left the conflict to be resolved by it . . ." "The jury's resolution of the fact conflict in favor of Winthrop removes all basis for liability to the retailer . . ."

III.

THE RECORD CONTAINS EVIDENCE SUFFICIENT TO SUPPORT THE JURY'S VERDICT AND NO ERROR WAS COMMITTED DURING THE TRIAL SUFFICIENT TO REQUIRE A REVERSAL.

1. THE INSTRUCTIONS: Taken as a whole, the instructions adequately informed the jury as to the issues.

2. PLAINTIFF'S CONTRIBUTORY NEGLIGENCE: The Court of Appeals overlooked the full import of the entire testimony relating to plaintiff's conduct. A triable issue of fact was clearly presented.

3. STATUTE REGARDING PHARMACISTS' RECORDS: The Court of Appeals misapprehended the basis for the introduction of this statute. The evidence related to the question of druggist Bornstein's credibility. One of the most sharply contested issues in the case concerned the action of druggist Bornstein in providing Aralen tablets to plaintiff from 1957 to 1964 on the basis of only one written, non-refillable prescription written in March of 1957 by Dr. Hoit. Both Bornstein and plaintiff claimed that thereafter Dr. Hoit gave various telephone prescriptions. These were supposed to have been reduced to writing by Bornstein, but only one was produced—the very dubious piece of paper

written by Bornstein's employee, John Klemis, supposedly on 4-29-57. This was completely at variance with the testimony of Dr. Hoit. Bornstein claimed he had thrown away all his later records on Mrs. Singer. In this context the record-keeping statute was clearly relevant on the question of Bornstein's credibility.

4. DR. TUFFANELLI'S TEACHING FILM: Dr. Tuffanelli, one of the country's outstanding authorities on lupus, and the only medical witness to testify who could claim long experience in dealing with the disease, stated unequivocally that lupus erythematosus was a single disease entity, serious and incurable, that can affect all parts of the body, and that it can and does cause retinopathy. He further stated qualified ophthalmologists differ as to whether one can say with any certainty if a given retinopathy is caused by chloroquine ingestion or by disease (R 2157-60). The film evidence was thus entirely proper in light of Dr. Tuffanelli's testimony.

CONCLUSION

For these reasons, a writ of certiorari should issue to review the judgment and opinion of the United States Court of Appeals for the Seventh Circuit.

Respectfully submitted,

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Sterling Drug, Inc.

July 20, 1972

In the
United States Court of Appeals
For the Seventh Circuit

No. 18607 SEPTEMBER TERM, 1970 APRIL SESSION, 1971

ANNA T. SINGER and LESLIE SINGER,
Plaintiffs-Appellants,

v.

STERLING DRUG, INC.,
Defendant-Appellee.

Appeal from the United States District Court for the Northern District of Illinois, Eastern Division.
No. 65-C-1221
JAMES B. PARSONS,
Judge.

APRIL 21, 1972

Before SWYGERT, *Chief Judge*, KILEY and FAIRCHILD, *Circuit Judges.*

KILEY, *Circuit Judge.* Plaintiffs Anna and Leslie Singer, husband and wife, brought this diversity action to recover damages for personal injuries alleged to have been caused by Anna Singer's ingestion of Aralen, a drug product of defendant Sterling Drug, Inc. Verdict and judgment were for Sterling, and plaintiffs appeal. We reverse and remand.

Anna Sterling began taking Aralen for a facial rash under a written prescription from Dr. Hoit, a dermatologist, in 1957. He had diagnosed the rash as discoid

lupus erythematosus.[1] Between 1957 and 1960 the doctor also gave oral prescriptions to pharmacists for Anna Singer's use. She continued taking Aralen until 1964, when she received notice from a pharmacist that the drug had a deleterious side effect. She again went to Dr. Hoit.

Thereafter, in 1964, Anna Singer was examined by Dr. Potts, an opthalmologist, who found her "visual field was constricted, that side vision had been lost, and that in addition central vision was diminished." Later examination by Dr. Potts disclosed extensive damage to the rod cells of Anna Singer's retina. The suit before us followed, alleging that the blindness, chloroquine retinopathy, was caused by the ingestion of Aralen.

The complaint was in four counts. In counts 1 and 2 Anna Singer claimed damages of $1,200,000 because of blindness proximately caused by Aralen.[2] In counts 3 and 4 Leslie Singer claimed damages of $35,000 for loss, among other things, of his wife's companionship and for deprival of her services during her blindness. Counts 1 and 3 were based on strict liability, and counts 2 and 4 on negligence. The jury returned verdicts against plaintiffs, and the judgments appealed from followed.

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[1] "A superficial inflammation of the skin marked by disklike patches with raised reddish edges and depressed centers, and covered with scales or crusts. These fall off, leaving dull white cicatrices." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY, 854 (24th ed. 1965).

[2] Plaintiffs' theory under the strict liability counts was that Sterling's liability was caused by its failure to adequately warn of the danger of Aralen. Defendant's theory was that it was not liable because of the prescription drug exception to the strict liability doctrine expressed in Comment *k*, § 402A of the RESTATEMENT (SECOND) OF TORTS (1965). Plaintiffs expressly stated there was no contention that Aralen was not manufactured according to its chemical formula or had a substance not in that formula.

I.

Plaintiffs contend that the district court's instructions rendered recovery impossible.

A. The district court erroneously instructed the jury on plaintiffs' strict liability counts in that the court used the term "wilfully and intentionally" in describing four allegations with respect to strict liability. The court also instructed the jury that plaintiffs had alleged in the strict liability counts that Sterling had not manufactured Aralen in accordance with its proper chemical formula. The court also stated that Sterling's answer framed the issue to be whether Sterling had been guilty of wilful and intentional misconduct.

The complaint alleged neither wilful and intentional misconduct on Sterling's part nor failure of Sterling to manufacture chemically pure Aralen. Under Indiana law the doctrine of strict liability does not require that Sterling be shown to have been guilty of wilful and intentional misconduct. *Cornette v. Searjeant Metal Products, Inc.*, 258 N.E.2d 652 (Ind. App. Ct. 1970); *Perfection Paint & Color Co. v. Konduris*, 258 N.E.2d 681 (Ind. App. Ct. 1970). The instruction placed a heavier burden on plaintiffs than was justified. The instruction was also faulty in placing the burden on plaintiffs of proving that the drug was not "in accordance with its chemical formula." This was not a theory of plaintiffs at trial. The giving of the instruction is clearly reversible error.

Defendant argues that its duty to warn is the same under both strict liability and negligence counts and that accordingly the erroneous instruction was cured. We are not persuaded. The effect of the instruction was to impose on plaintiffs a heavier burden to prove that element under the strict liability count than under the negligence count.

Sterling argues that the Singers must prove a failure by Sterling to warn about a known risk in taking Aralen before the doctrine of strict liability applies. Sterling relies on Comment *k* of § 402A of the RESTATEMENT (SECOND) OF TORTS (1965) for its position that all prescription drugs are covered by this exception to the strict liability doctrine.

Comment *k* establishes two classifications of drugs which are exceptions to the strict liability doctrine:

1) Drugs in which there is a known but apparently reasonable risk of injury and the user has been warned of the risk, *i.e.*, the Pasteur vaccine for rabies.

2) Drugs which are new and experimental for which there is no knowledge of the risk and the user has been warned that this is a new and experimental drug.

If we were to adopt Sterling's reading of Comment *k*, we would have to exclude all prescription drugs from coverage under the doctrine of strict liability and apply the negligence standard to them.

We shall assume, *arguendo*, that the Indiana courts adopted Comment *k* as Indiana law when they adopted § 402A of the RESTATEMENT (SECOND) OF TORTS. We hold that there is insufficient evidence in this case to show that Aralen fell into either category of drugs which are exceptions to the strict liability doctrine because (1) there was no general warning until March of 1963 of the side effects of causing chloroquine retinopathy, and (2) Aralen was neither a new and experimental drug nor a drug with a known but apparently reasonable risk.

B. In another instruction the court repeated the same clear error by stating, in effect, that if plaintiffs carried

the onerous burden, assigned to them by the court, Sterling would be strictly liable unless Anna Singer "did affirmatively assume a risk" in taking Aralen. Any question of Anna Singer's "misuse" or other misconduct is a matter of defense. *Perfection Paint & Color Co. v. Konduris, supra* at 688. Sterling asserted no defense of, and proffered no instructions upon, assumption of risk, and neither party considered it applicable here.

Application of the doctrine of assumption of risk presupposes knowledge of the danger which gives rise to the risk. *Pfisterer v. Grishom,* 137 Ind. App. 565, 572, 210 N.E.2d 75, 78-79 (1965). In *Greeno v. Clark Equipment Co.,* 237 F. Supp. 427, 429 (N.D. Ind. 1965), relied on by Sterling, the court was discussing "misuse" and stated, "Incurring a *known and appreciated* risk is a defense." (Emphasis added.) There is no evidence that Anna Singer had knowledge of the danger which would give rise to the risk. This error was repeated in still another instruction on the "two theories of liability." The court's instruction presupposes knowledge of plaintiff Anna Singer of the dangerous character of Aralen, but there was no such knowledge.

C. The court's assumed risk instruction also implied that the violation by Anna Singer's pharmacist of Indiana law by failing to keep records of prescriptions or by refilling the Aralen prescription without order of Dr. Hoit was evidence favorable to Sterling. This theory has been rejected. *Cf. Sterling Drug, Inc. v. Cornish,* 370 F.2d 82, 85 (8th Cir. 1966).

The court's giving of the prejudicially erroneous instructions requires granting a new trial to plaintiffs.

II.

When the evidence was closed, plaintiffs moved to withdraw the issue of contributory negligence from the jury on the ground there was no evidence of negligence on the part of Anna Singer proximately causing her blindness. Sterling says there is evidence of lack of due care in Anna Singer's taking a large quantity of Aralen tablets for a seven month trip to Spain, Italy, Morocco and Tunisia, in July, 1963, and in Dr. Hoit's advice to avoid sun and take double dosage if she was exposed to sun. The advice of Dr. Hoit about double dosage was not misconduct on her part, and the evidence does not show to what extent she was exposed to sun. Sterling argued that all of its literature advised that the recommended "maintenance dosage" was one 250 milligram tablet a day and that Anna Singer took an excessive amount of Aralen by taking two tablets per day; but some labels on the Aralen bottles advised that the "usual dosage" was two 250 milligram tablets a day. We think the evidence was too thin for submission to the jury of the issue of contributory negligence.

III.

The court erred in admitting evidence of an Indiana statute[3] requiring pharmacists to file and keep pre-

[3] Section 63-1219 provides: All original prescriptions shall be numbered and filed in numerical and chronological order and preserved for a period of at least five [5] years in the pharmacy. Such files shall be open for inspection to any member of the pharmacy board or its duly authorized agent or employee. No prescription for any drug, the label of which bears the following legend "federal law prohibits dispensing without prescription," shall be refilled without written or oral authorization of the practitioner licensed by law to administer such drug. The pharmacist refilling such prescription shall record the date of refill, together with the amount dispensed and the dispenser's initials on the original prescription. Prescriptions for narcotics shall be governed by the laws relating to narcotics. [Acts 1959, ch. 155, § 7, p. 378] BURNS' INDIANA ANNOTATED STATUTES.

scription records for five years. There was evidence that Anna Singer's pharmacist had no written records of Dr. Hoit's prescriptions, after 1957. But the evidence had no bearing on defendant's liability and could have had a harmful effect on plaintiffs' case. The error in the court's ruling is pointed up by the discussion in *Sterling Drug, Inc. v. Cornish, supra.*

IV.

Defendant was permitted to show a twenty minute motion picture with sound to the jury without first showing relevancy to the court. The film portrayed various types and stages of the disease lupus erythematosus, including terminal stages. It was designed to show the seriousness and incurability of Anna Singer's disease and to prove that retinopathy can be caused by lupus erythematosus. The court, upon objection that the film had relevancy neither to chloroquine retinopathy nor to the seriousness of Anna Singer's lupus erythematosus which had affected only facial skin, stated that the film would be stricken if not "connected up." The defendant failed to connect the movie to this case since there was no testimony that Anna Singer suffered from retinopathy caused by lupus erythematosus rather than chloroquine retinopathy. Yet the film was not stricken, and the failure to strike was error.

V.

At the close of all of the evidence, the district court judge denied plaintiffs' motion for a directed verdict as to liability and their request that only the issue of damages be submitted since strict liability had been shown as a matter of law. Sterling contends that there is an issue of fact as to misuse of Aralen by Anna Singer; that the evidence shows that Anna Singer was warned by Dr.

Hoit to avoid summer sun and yet proceeded to spend several months in "the hottest sun" of Southern Europe and North Africa; and that she used Aralen so excessively that she exhausted her supply of the 100 tablets she brought for her seven month stay in Europe.

We have read the testimony relied on by Sterling and find no substantial evidence of Anna Singer's misuse of Aralen through excessive dosage or through "exposure to hot sun" during her European trip.

We conclude therefore that there was insufficient evidence that plaintiff misused Aralen during the relevant period. Consequently we hold that the district court erred in refusing to grant plaintiffs' motion for a directed verdict on the issue of strict liability since plaintiffs had proven as a matter of law their case under the theory of strict liability. The Singers proved that Sterling, with knowledge of the risks of Aralen causing chloroquine retinopathy, failed to give adequate warning to those who, like Dr. Hoit, would prescribe Aralen to their patients. The Singers proved a stronger case than required since the doctrine of strict liability would hold Sterling liable for manufacturing and marketing, without adequate warning, a dangerously defective product like Aralen.

Other questions raised we deem unnecessary to decide because in the trial of the damages issue they will not be relevant. Questions of other prejudicial comments by the judge or provocative conduct of plaintiffs' counsel inducing prejudicial comments are not discussed.

It is ordered that the judgment of the district court be reversed and the case remanded for a new trial as to damages. Under Rule 23 of the local appellate rules of this court—adopted and promulgated on April 4, 1972—this case on remand should be reassigned by the district

court for trial before a judge other than the judge who heard the original trial, unless all parties request that the same judge retry the case.

REVERSED AND REMANDED.

A true Copy:

Teste:

.....

Clerk of the United States Court of Appeals for the Seventh Circuit.

United States Court of Appeals

For the Seventh Circuit

Chicago, Illinois 60604

JUNE 5, 1972

BEFORE

Hon. LUTHER M. SWYGERT, *Chief Judge*
Hon. ROGER J. KILEY, *Circuit Judge*
Hon. THOMAS E. FAIRCHILD, *Circuit Judge*

ANNA T. SINGER AND LESLIE SINGER, *Plaintiffs-Appellants,* vs. No. 18607 STERLING DRUG, INC., *Defendant-Appellee.*	Appeal from the United States District Court for the Northern District of Illinois, Eastern Division. (65 C 1221)

On consideration of the petition for rehearing and suggestion that it be heard *en banc* filed in the above-entitled cause, no judge in active service having requested a vote thereon, nor any judge voted to grant the suggestion, and all members of the panel having voted to deny a rehearing,

IT IS ORDERED that the petition for a rehearing in the above-entitled cause be and the same is hereby denied.

APPENDIX II

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In The

Supreme Court of the United States

October Term, 1972

No. 72-113

STERLING DRUG, INC.,

Petitioner,

vs.

ANNA T. SINGER and LESLIE SINGER,

Respondents.

BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

PREFATORY NOTE.

Petitioner, Sterling Drug, Inc., does not set forth any jurisdictional grounds upon which its petition is based. Rather it states its basis is 28 U.S.C. 1254(1). Nowhere is this Court's Rule 19 referred to nor any of the reasons stated therein urged as a basis of jurisdiction.

Actually, the essence of the petition is that the Court of Appeals should have arrived at a different conclusion and should not have exercised its power to remand for trial on the issue of damages only.

THE QUESTION PRESENTED.

More properly stated the question is: Should this Court interfere with the interlocutory order of the Court of Appeals which on review finds the only issue between the litigants is that of damages?

REASONS FOR DENIAL OF THE PETITION.

Petitioner's sketchy factual statement requires an addendum.

The uncontradicted proof was:

(a) Aralen causes chloroquine retinopathy;

(b) Mrs. Singer's blindness was due to ingestion of Aralen;

(c) Since 1958, petitioner knew that Aralen caused this condition;

(d) There were multiple cases of serious visual disturbance, including blindness, reported in Aralen users over this period but it was not until February 1963, that petitioner sent a letter to the medical profession. It continued to market this drug.

Petitioner's statement that "the crux of the dispute" (Pn. p. 2) was whether respondent had improperly obtained refills of an original prescription is not only an innuendo but not the fact. Moreover, this could not con-

stitute a defense as a matter of law to this strict liability in tort action.

Its statement that "it was undisputed that plaintiff was suffering from a chronic incurable disease known as lupus erythematosus which can cause blindness . . ." (Pn. p. 2), is incorrect. On the contrary it was uncontradicted testimony of outstanding opthalmologists such as two professors of Opthalmology of the University of Chicago Medical School that the respondent suffered from a chloroquine retinopathy or damage to the retina of the eye caused by the ingestion of Aralen, the trade name for the drug chloroquine. (R. 70, 251, 2462) As the opinion noted: "the defendant failed to connect the movie in this case since there was no testimony that Anna Singer suffered from retinopathy caused by lupus erythematosus rather than chloroquine retinopathy." (Pn. p. 7a)

The want of timeliness of the warning and its insufficiency is apparent from a few facts.

On October 10, 1958, Dr. Bagnall, an experimenter for petitioner, wrote petitioner's Dr. Rice (Pltfs' Ex. 35), describing two cases of visual impairment in Aralen users.

Attached to that letter of Dr. Bagnall was written in handwriting:

> "3/25/60. Do not advise FDA now. Send lit. when reprinted including corneal changes & say it is modified version of what we subm. several months & which they passed on. Discussed w/Dr. Foley & Dr. Rice."

At no time did the defendant explain why this letter of October 10, 1958, was withheld from the Food and Drug Administration.

In the years 1959, 1960, 1961, 1962, 1963, and thereafter medical literature was flooded with reports showing Aralen to be the incriminating factor in loss of vision in its users.

Dr. Foley, petitioner's medical director, as early as June, 1960, (Pltfs' Ex. F 196), prepared a proposed warning concerning retinal changes as the result of Aralen. It did not send out any warning until 1963.

On December 2, 1959, petitioner's Dr. C. H. Roth wrote its Dr. J. B. Rice that an examination of defendant's files revealed instances in which retinal changes were observed in persons taking Aralen. (Pltfs' Ex. 271)

In evidence were memoranda and letters from practicing physicians, petitioner's agents, as well as lay persons, about loss of vision in Aralen users. These commenced in 1958). (Pltfs' Exhibits 174, 329, 331, 338, 342, 344, 315A, 277, 314, 40A, 197 F6.)

The Physicians' Desk Reference is circulated through the medical profession. The particular drug company writes its advertising copy for this important book. (R. 604)

Throughout the years from 1955 to 1961, the Desk Reference's description of Aralen contained no warning whatsoever as to serious visual side effects.

In 1962, when Aralen was a recognized cause of retinal change, petitioner for the first time since 1957, failed to list Aralen although it was marketed.

In 1963, it first listed irreversible changes in the retinae of users. (Pltfs' Exhibit 52)

THERE WERE NO ISSUES OF FACT ON THE QUESTION OF LIABILITY; PETITIONER DID NOT, AT THE TRIAL, CHALLENGE THE CHARACTER OF THE DRUG AND THE CAUSE OF ANNA SINGER'S BLINDNESS; ITS DEFENSIVE EFFORTS WENT TO HER CONDUCT WHICH COULD NOT, AS A MATTER OF LAW BE A DEFENSE.

In much of its litigation petitioner has sought to shift its obligation to some third person such as druggist or doctor. (*Sterling Drug, Inc.* v. *Cornish*, 370 F. 2d 82 (8 Cir. 1966); *Kershaw* v. *Sterling Drug, Inc.*, 415 F. 2d 1009, (5 Cir. 1969); *Krug* v. *Sterling Drug, Inc.*, (Mo.) 416 S.W. 2d 143 (1967) and *Schenebeck* v. *Sterling Drug, Inc.*, 291 F. Supp. 368, 423 F. 2d 919 (8 Cir. 1970).)

In *Cornish*, *Kershaw* and *Krug*, the druggist(*) was sought to be interposed as a defense, while in *Schenebeck*, it was the doctor, who had given plaintiff a refillable prescription which was used for four years without medical supervision.

Here, petitioner sought to interpose Anna Singer's conduct as a defense, notwithstanding that assumption of risk under the Indiana controlling law would be the only vehicle of questioning her conduct. There was, admittedly, no evidence of assumption of risk. Petitioner tried this

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(*) In both the *Kershaw* and *Cornish* cases, this instruction was given:

"However, if you believe from the evidence that even though the druggist did not obtain the approval of the individual prescribing doctor for the refilling of such prescriptions, if you also find from the evidence that the doctor knew and authorized the plaintiffs to obtain such refills and continued to treat each plaintiff with the knowledge that she was taking said medicine, then the fact that they may have been refilled by the druggist in violation of the law, would not prevent either plaintiff from recovering if she was otherwise entitled to recover."

case as if it were a negligence action, with contributory negligence an issue.

The Court of Appeals observed: "The Singers proved a stronger case than required since the doctrine of strict liability would hold Sterling liable for manufacturing and marketing, without adequate warning, a dangerously defective product like Aralen." (p. 82)

MISUSE OF ARALEN.

The argument concerning misuse is without foundation in law or in fact. Misuse is a use by the consumer which was not reasonably foreseeable. (*Thomas* v. *General Motors*, 91 Cal. Rptr. 301, 306 (1971).)

Obviously taking a drug made to be consumed by such members of the public as the respondent is a foreseeable use.

Dwelling on Anna Singer's conduct, petitioner suggests an issue that her lupus condition was aggravated by her "exposure to hot sun." The Court of Appeals found no evidence to support this contention. (Pn. p. 8a)

Nor was there any evidence of acerbation or remissions of lupus. On the contrary, she had no evidence of this condition for several years. Dr. Tuffanelli did not state lupus could cause retinopathy, as the Court of Appeals points out. (Pn. p. 7a) Dr. Tuffanelli not only failed to express any relationship between Mrs. Singer's eye condition and the lupus condition (R. 2717-18), but said he was not an expert concerning eye conditions. (R. 2123)

Petitioner's comments concerning excessive dosage are interesting. Petitioner on its own label states: "Usual

dose: 2 tablets," and again "Usual dose: 20 to 4 tablets." (Pltfs' Exhibit 11)

Respondent Anna Singer took two tablets daily in accord with these directions.

The Physician's Desk Reference, written by defendant (R. 604), does not refer to dosage as a factor in side effects, even in the 1963 Edition. (Pltfs' Exhibit 52)

The product information card suggesting periodical ophthalmological examinations is immaterial. Dr. Hoit, who prescribed the drug, did not have any of his patients on Aralen obtain eye examinations. (R. 1686-1693) His conduct could not be a defense.

Petitioner's statement that respondent did not see any physician in 1963 before taking a trip, is not only contrary to the record (R. 1360) but immaterial.

PETITIONER'S DUTY TO PLAINTIFF WAS NON-DELEGABLE; THE CONDUCT OF A THIRD PARTY COULD NOT CONSTITUTE A DEFENSE.

Dr. Hoit gave Anna Singer a written prescription dated April 29, 1957 (Pltfs' Exhibit 381A) and wrote the referring doctor thanking him for sending Mrs. Singer to him. (Pltfs' Exhibit 409)

Proof of the prescription of the drug (Pltfs' Exhibits 381A, 381B, 416) was made by three pharmacists. (R. 1069, 1074, 1079, 1090, 1091) Dr. Hoit's records were lost in 1963 when a cleaning woman employed by the building erroneously threw them out. (R. 893, 894) He did not recall Mrs. Singer upon being shown the prescription in his longhand or the letter in his handwriting to the forwarding doctor. He could not recall the respondent with-

out records. He made it clear, however, that he did not deny that Mrs. Singer was his patient or that he treated her during 1957, 1958, 1958, 1960, 1961 and 1963 for the lupus condition. (R. 1615, 1616, 1619-21)

Indeed, if Dr. Hoit had given respondent a refillable prescription in 1957 and had never seen her, petitioner could not avoid responsibility for the character of the drug which it described as one which was to be persistently used. (Pltfs' Exhibit 12A) (*Schenebeck* v. *Sterling Drug, Inc.*, 291 F. Supp. 368 (E.D. Ark.), 423 F. 2d 919, 923 (8 Cir. 1970)

There is no intervening cause recognized here (*Zahora* v. *Harnischfeger Corp.*, 404 F. 2d 172, 177 (7 Cir. 1968), construing Indiana Law; *Sterling Drug, Inc.* v. *Cornish*, 370 F. 2d 82, 85 (8 Cir. 1966); *Schenebeck* v. *Sterling Drug, Inc.*, 291 F. Supp. 368, 423 F. 2d 919, 922 (8 Cir. 1970).)

The conduct of the treating doctor has long been recognized as not imputable to the plaintiff in an action against a drug manufacturer. (*Schenebeck* v. *Sterling Drug, Inc.*, 291 F. Supp. 368, 423 F. 2d 919, 922 (8 Cir. 1970); *Kershaw* v. *Sterling Drug, Inc.*, 415 F. 2d 1001, (5 Cir. 1969); *Mochlenbrock* v. *Parke, Davis and Co.*, 141 Minn. 154, 169 N.W. 541, 544 (1918); *Abbott Laboratories* v. *Lapp*, 78 F. 2d 170 (7 Cir. 1935).)

The issues here were the character of the drug and whether it was a proximate cause of respondent's condition of ill-being. (Restatement of the Law of Torts, 402A) Nor was this an unavoidable unsafe product within Comment k of 402A of the Restatement of the Law of Torts. The Court of Appeals discussed this contention at length. (Pn. p. 4a)

OTHER ARALEN CASES.

Other Aralen cases are of little assistance because:

(a) The record in each case was different with the defendant in many situations questioning the character of the drug—a strategy not employed here;

(b) The laws of different jurisdictions were involved. This action was governed by Indiana law;

(c) Almost all proceeded on the theory of negligence, while petitioner does not deny the applicability of the doctrine of strict liability in tort;

(d) In a vast majority, the plaintiff recovered and that judgment was affirmed on appeal; and

(e) Different periods of time were involved. Specifically, many cases were tried earlier when the available proof had not existed. As an example, *Krug* v. *Sterling Drug, Inc.*, 416 S.W. 2d 142 (1967), involved the use of the medication as far back as 1953.

Oppenheimer v. *Sterling*, 7 Ohio App. 2d 103, 219 N.E. 2d 54, (1964) involved a directed verdict for the defendant.(*) *Oppenheimer* refers to the intervening causal conduct of doctor and druggist but no intervening cause exists here. (*Zahora* v. *Harnischfeger Corp.*, 404 F. 2d 172, 177 (7 Cir. 1968); *Sterling Drug, Inc.* v. *Cornish*, 370 F. 2d 82, 85 (8 Cir. 1966); *Schenebeck* v. *Sterling Drug, Inc.*, 291 F. Supp. 368, 423 F. 2d 919, 922 (8 Cir. 1970).) It is a matter of record that the petitioner settled the case after the Ohio intermediate court opinion.

(*) In answer to an interrogatory asking for the name of the claimant, the Court, the date of last ingestion, the product and status, defendant responded: "Faye Oppenheimer, Common Pleas Court, Franklin County, Ohio, date of last ingestion November, 1960, Aralen, and under status: Settled—Defendant's verdict affirmed on appeal." (C.R. 70, p. 17)